



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 46851-12

Date of Issuance: MAY 15 2014

Term of Issuance: Conditional

Name of Pesticide Product: ProSpray Wipes

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Certol International, LLC
6120 East 58th Avenue
Commerce City, CO 80022

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/ reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. D-477344) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for reregistration /registration review of your product under FIFRA sec. 3(c)5 when the Agency requires all registrants of similar products to submit such data.
2. Submit a storage stability (OPPTS Guideline 830.6317) and corrosion characteristics study (OPPTS Guideline No 830.6320) one year from the date of the registration notice.
3. Submit one copy of the final printed label before distributing or selling this product.

A stamped accepted label is enclosed for your records. Should you have any questions regarding this letter, please contact me by telephone at (703) 308-6416 or by email at Campbell.jacqueline@epa.gov or Stacey Grigsby by telephone at (703)305-6440 or by email at grigsby.stacey@epa.gov.

Signature of Approving Official:

Signature of Jacqueline Hardy
Jacqueline Hardy, Product Manager Team-34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

MAY 15 2014

2711

Certol[®] International

[Kills [99.9% of] [viruses] [and] [bacteria] [in 3 minutes]]

ProSpray™ wipes

[Surface Disinfectant] [/] [Cleaner] [Towelettes]

["One-Step"] [Cleaner] [/] [Disinfectant] [/] [Deodorizer]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against Section.]

[Tuberculocidal] [,] [[Virucidal]*] [,] [Bactericidal] [,] [Fungicidal]

[Kills Staphylococcus aureus - MRSA HA [in three minutes]]

Active Ingredients

o-phenylphenol	0.647%
o-benzyl-p-chlorophenol	0.070%
Inert Ingredients	99.283%
Total	100.000%

E.P.A. Reg. No. 46851-12

E.P.A. Est. No. 46851-CO-003

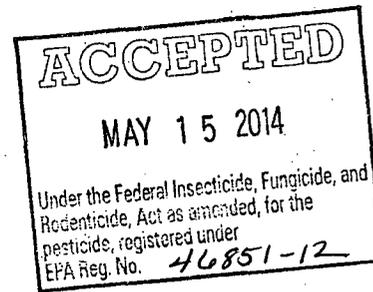
[Lot #] [and] [expiration date] [printed on container]

[_____] [Pre-moistened] [Towelettes]

[[_____ in. x _____ in.] [(_____ cm x _____ cm)]]

[Reorder No: _____]

Net Contents: [_____] [lbs.] [_____] [oz.]



Keep Out of Reach of Children

CAUTION

[See other panels for additional precautionary statements.]

[THIS IS NOT A SKIN WIPE]



[THIS IS NOT A BABY WIPE]

[PRODUCT BARCODE:] [+H816 _____]

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FIRST AID:

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

HOTLINE NUMBER: In case of an emergency call toll free 1-800-535-5053.

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

USER SAFETY REQUIREMENTS: Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. [Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.]

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".]

DESCRIPTION: ProSpray™ wipes are [non-woven] [,] [non-abrasive] [disposable] [towelettes] presaturated with ProSpray™ Disinfectant. [ProSpray™ wipes are [an effective ["one-step"] cleaner] [and] [intermediate-level] [disinfectant] [according to the AOAC Use-Dilution Test]] [,] [modified in the presence of 5% organic soil load] [and] [meets AOAC efficacy standards for hospital-use disinfectants.]] [This product [cleans] [,] [disinfects] [and] [deodorizes] [hard non-porous surfaces] [in one labor-saving step]]. [ProSpray™ wipes may be used in [healthcare,] [office,] [transport,] [commercial] [and] [home settings] [on] [vinyl,] [plastics,] [metals,] [floors,] [walls,] [counters,] [carts] [and] [bedside equipment.]]

[Choose one of the following directions based on packaging]

[a. Canister]

[TO OPEN PACKAGE: Open cap lid and pull up firmly using lid to remove the entire cap from canister. Remove protective seal. Locate wipe at the center of the roll and insert corner of wipe through opening in lid. Replace lid. Pull wipe up and slightly to the side. The next wipe pops up automatically. Always snap lid securely shut between uses to prevent moisture loss.]

[b. Soft Pack]

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4811

[PREPARATION OF DISPENSER: Lift up tab and pull back to expose the entire opening. Do not remove Peel & Seal tab. Grasp exposed edge of towelette and pull out. Close Peel & Seal tab to prevent evaporation by returning it to its original position and press down firmly.]

[ProSpray™ wipes are effective against the following microorganisms on hard, non-porous surfaces when used as directed:]

[EFFECTIVE AGAINST:]

[MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS [(TB)]]

[STAPHYLOCOCCUS AUREUS]

[STAPHYLOCOCCUS AUREUS - MRSA HA]

[SALMONELLA ENTERICA]

[PSEUDOMONAS AERUGINOSA]

[[*]HIV-1 [(AIDS VIRUS)]]

[[*]HERPES SIMPLEX VIRUS TYPES 1 & 2]

[TRICHOPHYTON MENTAGROPHYTES [(FUNGUS)]]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[DO NOT USE AS A BABY WIPE.] [NOT FOR USE ON SKIN.] [DO NOT FLUSH WIPE.]

[Must not be used in hospital nurseries.]

[The following paragraph will be included in its entirety when the production label references healthcare use.]

ProSpray™ wipes are designed for use on hard non-porous surfaces. This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

CLEANING: ProSpray™ wipes are an effective ready-to-use cleaning agent. [Occasional rinsing or wiping with damp cloth is recommended when ProSpray™ wipes are used frequently on floors, stainless steel, vinyl and other hard surfaces.]

FOR USE AS A ONE-STEP CLEANER/DISINFECTANT: Pre-clean heavily soiled areas.

[ProSpray™ wipes may be used for this step.] [Discard used wipes after pre-cleaning.] Remove one or more fresh ProSpray™ wipes Disinfectant Towelette(s), unfold, wipe surface thoroughly. If areas are not heavily soiled, clean and disinfect with one wipe. All surfaces must remain visibly wet for 3 minutes.

CONTACT TIME:

[ONE MINUTE EXPOSURE:]

[HIV-1 [(AIDS virus)]] [,] [Herpes simplex virus types 1 & 2]

[THREE MINUTE EXPOSURE:]

[Mycobacterium tuberculosis var. bovis [(TB)]] [,] [Staphylococcus aureus] [,]

[Staphylococcus aureus - MRSA HA] [,] [Salmonella enterica] [,] [Pseudomonas aeruginosa] [,]

[Trichophyton mentagrophytes [(Fungus)]]

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[The following HIV instructions are to be included on production labels when claims against HIV are listed.]

ProSpray™ wipes kill HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 HIV-1 [(associated with AIDS)].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of ProSpray™ wipes. [ProSpray™ wipes may be used for this purpose.]

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

CONTACT TIME: Allow surface to remain wet for one minute to kill HIV-1 [(AIDS Virus)] and Herpes simplex virus types 1 & 2. Use a three minute contact time for TB, Staphylococcus aureus, Staphylococcus aureus - MRSA HA, Salmonella enterica, Pseudomonas aeruginosa and Trichophyton mentagrophytes (Fungus).

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store at room temperature in original container in an area inaccessible to persons unfamiliar with its use. Tightly close lid between uses to retain moisture.

PESTICIDE DISPOSAL: Do not reuse towelettes. Dispose of used towelette and empty container in regular trash. Do not flush used towelettes. To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

[Choose one of the following disposal directions based on packaging]

[a. Canister]

[CONTAINER DISPOSAL: Non-refillable canister. Do not reuse or refill this canister. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.]

[b. Soft Pack]

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6811

[CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.]

[Optional Marketing Claims:]

[Lemon Scent.]

[Fresh Scent.]

[AREAS OF USE:]

[NURSING, HOSPITAL AND HEALTHCARE SETTINGS:]

[[Ambulatory Surgical Centers]][(ASC)]

[Anesthesia]

[Cat Labs]

[CCU]

[Central Supply Clinics]

[Clinics]

[Dental Offices]

[Dialysis]

[Doctors' Offices]

[Donation Centers [(Apheresis, Blood, Milk, Plasma, Semen)]]

[Emergency Medical Settings]

[Emergency Rooms]

[Eye Surgical Centers]

[Hospices]

[ICU]

[Isolation Areas]

[Laboratory]

[Laundry Rooms]

[[Operating Rooms]][(OR)]

[Ophthalmic Offices]

[Orthopedics]

[[Out-patient Surgical Centers]][(OPSC)]

[Patient Care Areas]

[Physical Therapy]

[Radiology]

[Reception Areas]

[Recovery Rooms]

[Rehabilitation]

[Respiratory Therapy]

[Surgery]

[Waiting Room]

[OFFICE AND HOME SETTINGS:]

[Libraries]

[Manufacturing Facilities]

[Office Buildings]

[Public Facilities]

[Cabinets]

[Computers]

[Counters]

[Desks]

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[OFFICE AND HOME SETTINGS (continued):]

- [Doorknobs]
- [Fax Machines]
- [Filing Cabinets]
- [Garbage Cans]
- [Headsets]
- [Keyboards]
- [Public Telephones]
- [Railings]
- [Seats]
- [Sinks]
- [Tables]
- [Tabletops]
- [Telephones]
- [Work Stations]

[EMERGENCY SERVICES SETTINGS:]

- [Ambulances]
- [Police Cars]
- [Transport Vehicles]

[VETERINARY SETTINGS:]

- [Isolation Areas]
- [Veterinary Clinic]
- [Waiting Room]

[HEALTH CLUB FACILITIES AND GYMS:]

- [Gym Equipment]
- [Locker Rooms]
- [Reception Areas]
- [Showers]

[BATHROOMS:]

- [Basins]
- [Bathroom Fixtures]
- [Bathtubs]
- [Cabinets]
- [Countertops]
- [Doorknobs]
- [Faucets]
- [Glazed Tiled Walls]
- [Hampers]
- [Handles]
- [Handrails]
- [Showers]
- [Sinks]
- [Toilet [(Handle, Rim, Seats, Tank, Other Exterior Surfaces)]]
- [Urinals [(Exterior Surface)]]
- [Vanity Tops]

[TRANSPORT SERVICE SETTINGS:]

- [Fire Trucks]
- [School Buses]
- [Transport Vehicles]
- [Hard Plastic or Metal Flooring]
- [Seats]
- [Steering Wheel]
- [Walls]

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[HARD NON-POROUS SURFACES:]

- [Adapter Rings]
- [Bed Frame]
- [Bidet]
- [Booster Seats]
- [Brass]
- [Chrome]
- [Clean-up Carts]
- [Copper]
- [Crystal]
- [Cuspidors]
- [Drains]
- [Dressing Carts]
- [Drinking Fountains]
- [Enamel]
- [Examination Tables]
- [Fixtures]
- [Floors]
- [Furniture [(Non Wood)]]
- [Glass]
- [Glazed Ceramic Tile]
- [Glazed Porcelain Tile]
- [Laminate]
- [Lamps]
- [Light Switches]
- [Linen Carts]
- [Linoleum]
- [Litter Boxes]
- [Marble [(Culture, Synthetic)]]
- [Marlite]
- [Metal]
- [Metal Blinds]
- [Mirrors]
- [Outdoor Furniture]
- [Parquet]
- [Patient Chairs]
- [Pens]
- [Plastic]
- [Plastic Mattress Covers]
- [Portable Toilet]
- [Recycling Bins]
- [Remote Controls]
- [Resilient [(Ceramic)] Floor]
- [Sealed Granite]
- [Sealed Wood]
- [Sports Equipment]
- [Stainless Steel]
- [Stretchers]
- [Tin]
- [Tools]
- [Vinyl]
- [Wheelchairs]
- [Whirlpool Interiors]

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[HARD NON-POROUS SURFACES (continued):]

[Windows]

[HARD NON-POROUS USE SITES:]

[Attic]

[Automobile]

[Basement]

[Bathroom]

[Bedroom]

[Boat]

[Cabin]

[Camper]

[Closet]

[Den]

[Dining Room]

[Dorm]

[Family][/][Living Room]

[Garage]

[Home]

[Kitchen]

[Laundry Room]

[Locker]

[Mobile Home]

[Mudroom]

[Pet Area]

[Public Places]

[Storage Area]

[Studio]

[Sunroom]

[Tool Shed]

[Workshop]

[HARD NON-POROUS PROFESSIONAL USE SITES:]

[Blood Bank]

[Clinic]

[College]

[Commercial Building]

[Correctional Facilities]

[Dental Office]

[Doctors' Office]

[Grocery Store]

[Gymnasium]

[Health Care Facility]

[Health Club]

[Hospital]

[Hotel][,][Motel]

[Kennel]

[Laboratory]

[Laundromat]

[Military Installation]

[Morgues]

[Mortuaries]

[Nursing Home]

[Office Building]

[Patient Room]

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[HARD NON-POROUS PROFESSIONAL USE SITES (continued):]

- [Pharmacy]
- [Public Places]
- [Recreational Center]
- [Restroom]
- [Shelter]
- [Sick Room]
- [Warehouse Club]

[ProSpray wipes are recommended for use in healthcare settings.]

[ProSpray wipes disinfectant towelettes are intended for use [on] [/] [in] medical [devices] [/] [settings].]

[ProSpray wipes [is]/][are] a multi-purpose [disinfectant][decontaminant] [cleaner] for use on hard, non-porous inanimate surfaces.]

[ProSpray wipes will effectively clean and disinfect, when used as directed; such items as [list]]

[FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES, INSTRUMENTS AND IMPLEMENTS: [Instruments must be thoroughly cleaned to remove excess organic debris [ProSpray wipes may be used for this step], rinsed and dried. Remove one or more fresh ProSpray wipes and apply to pre-cleaned surfaces, thoroughly wetting areas to be disinfected. Allow surfaces to remain visibly wet for 3 minutes at room temperature [(68°F / 20°C)]. Rinse instruments and wipe dry prior to use.]]

[Non-critical medical devices are items that come in contact only with intact skin.]

[ProSpray wipes are an effective method to clean against odor-causing organisms on hard, non-porous surfaces listed on this label.]

[Non-alcohol actives]

[Indicated for use when manufacturer's instructions direct that ~~recommend avoiding~~ alcohol [on] [vinyls] [or] [plastics] must be avoided.]

[No bleach actives]

[Water-based intermediate-level disinfectant]

[Broad based material compatibility]

[Reduced toxicity for frequent users]

[Easy and convenient way to clean and disinfect]

[So surfaces are more than just clean, they are disinfected.]

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11/2/11

[The following statement is to be included on production labels when food contact areas or surfaces are listed:]

[A thorough rinse with potable water is required for surfaces in direct contact with food.]

Certol® International

A Limited Liability Company

6120 East 58th Avenue
Commerce City, CO 80022 USA
Toll-free: (800) 843-3343
www.certol.com

WIPES/EPA/TX03 05/14

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